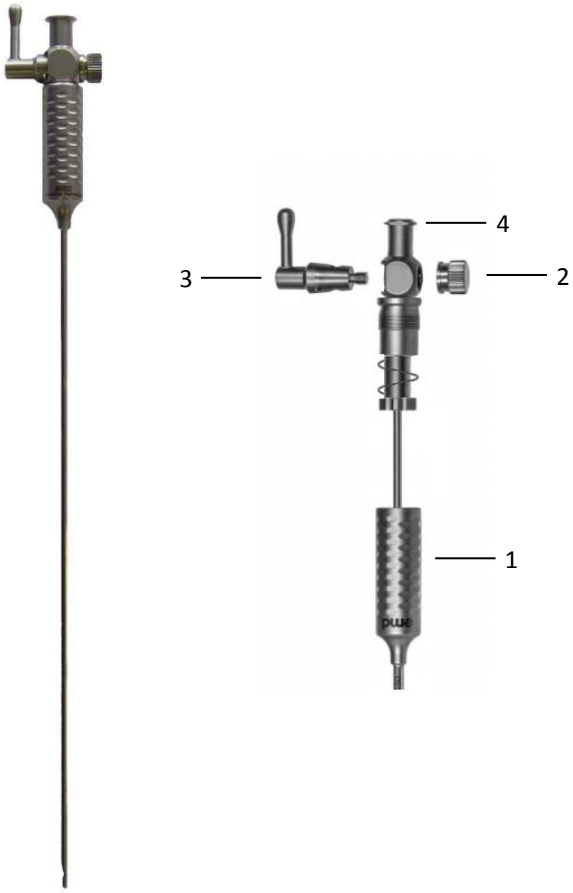
# Instruction for Use

## EndoLine Veress Needle




### I. Product range

ELV-080R, ELV-090R, ELV-100R, ELV-110R, ELV-120R, ELV-130R, ELV-140R, ELV-150R, ELV-160R, ELV-170R, ELV-180R

### II. Explanation of symbols

| | |
|---|---|
| | Manufacturer |
| REF | Catalogue number |
| | Caution |
| | Consult instruction for use |
| LOT | Batch code |
| CE 1011 | compliance with the Directive 93/42/EEC |

### III. Intended use

The device is intended to ensure pneumoperitoneum during laparoscopy.

### IV. Intended user

This product may only be used by experienced medical staff skilled in endoscopic applications.

### V. Contraindications

Absolute contraindications:

- severe heart disease
- hemorrhage
- bowel obstruction

Relative contraindications:

- multiply pre-operated patient
- morbid obesity
- pregnancy – from the fifth months of gestation
- anesthetic risk, anesthetic complications
- malignant tumor

### VI. Cautions

- **Risk of injury and/or malfunction!**
  - » Always perform a functional check before using this product.
  - » Replace sealing unit if necessary.
  - » To prevent damage to the sealing unit, apply appropriate care when inserting any instruments.

- **Potential risk to patients in case of inappropriate application!**
  - » Make certain the user is sufficiently trained and experienced in endoscopic surgical techniques, and familiar with the relevant anatomic features (blood vessels, structures).
  - » Prior to inserting the trocar in the patient, apply an abdominal pneumoperitoneum e.g. with a Veress cannula.
  - » Apply skin incisions in order to obviate excessive application of force.
  - » Position any further trocars under intra-abdominal visual control.

- **Malfunction due to incompatible instruments!**
  - » Check for mutual compatibility of the trocar system and instruments. To do this, carefully insert the instrument into the trocar and check for patency.

- **Damage to the product due to inappropriate cleaning/disinfecting agents and/or excessive temperatures!**
  » Apply chemicals approved for rigid endoscopes only.
  » Observe specifications regarding concentration, temperature and exposure time.

- **Risk of infection!**
  » If the device was used on a patient with an infectious disease, follow local guidelines for infectious patients.

- **Risk of injury and / or malfunction!**
  » Do not modify the product.
  » For service and repairs, please contact the manufacturer or the distributor.

## VII. Safe use

- Please be ensured that the product and its accessories are used and handled only by persons who have the appropriate knowledge and experience.
- Read and follow the operating instructions.
- Use the device only as intended, see "Intended Use".
- The new device must always be cleaned, disinfected and sterilized before the first use. First remove the shipping packaging and clean the device as specified (see below).
- Store any new or unused product in a dry, clean and safe place.
- Inspect the product and its components every time before use for damages (i.e. loose, bent, cracked, broken, worn, damaged) and for defect.
- Replace any defective component with an original replacement, if available. If not available, please contact the manufacturer or the authorized distributor.
- Do not use the product if it is damaged or defective. Damaged, defective product must be stored separately.
- Only combine trocar sleeves and trocar obturators with the same colour code (diameter) and the same working length.
- The metal and plastic parts of the devices can be subjected to 300 sterilization cycles, while their seals can be subjected to 50 sterilization cycles.

## VIII. Assembly

1. Place the spigot (3) in the valve body (4).
2. Screw the spring nut (2) onto the spigot (3).
3. Place the cutting cannula (1) on the blunt obturator and screw it fully.

## IX. Disassembly

1. Unscrew the cutting cannula (1) from the device.
2. Unscrew the spring nut (2) from the spigot.
3. Pull the spigot (3) out of the valve body (4).

## X. Cleaning and disinfection procedure

Cleaning of the device should be started within 30 minutes after surgical use.

The device must be cleaned only when it is fully disassembled (see section **Disassembly**).

**Validated cleaning/disinfection procedure:**

Automated cleaning/disinfection with manual pre-cleaning

| Phase | Steps | Temp [°C] | Time [min] | Conc [%] | Water quality | Reagent |
|---|---|---|---|---|---|---|
| **Manual pre-cleaning** | | | | | | |
| 1. | Manual pre-wash | 35 | 5 | 2 | Tap water | Sekusept Pulver |
| 2. | Ultrasonic cleaning | 30 | 5 | 2 | Tap water | Sekusept Pulver |
| **Automated cleaning/disinfection** | | | | | | |
| 3. | Pre-wash | 30 | 10 | 1 | Deionized water | Prolystica Ultra Concentrate |
| 4. | Washing | 90 | 30 | 2 | Deionized water | Prolystica Ultra Concentrate |
| 5. | Neutralize | 30 | 10 | 1 | Deionized water | Prolystica Ultra Concentrate |
| 6. | Rinsing | 30 | 10 | - | Deionized water | - |
| 7. | Drying | 90 | 10 | - | - | - |

1. ***Phase: Manual pre-wash.*** Prepare the specified solution. Place the disassembled device in the solution and wash the device for at least 5 minutes.
2. ***Phase: Ultrasonic cleaning.*** Prepare the specified solution in the ultrasonic bath. Place the disassembled device in the ultrasonic bath and wash the device for at least 5 minutes.
3. ***Phase: Pre-wash.*** The pre-wash phase of the washer-disinfector.
4. ***Phase: Washing.*** The wash phase of the washer-disinfector.
5. ***Phase: Neutralize.*** The neutralization phase of the washer-disinfector.
6. ***Phase: Rinsing.*** The rinsing phase of the washer-disinfector.
7. ***Phase: Drying.*** The drying phase of the washer-disinfector.

If the user is applying other cleaning phases and/or parameters, it is the user's responsibility to validate the cleaning procedure.

## XI. Checks and tests

- Allow the product to cool down to room temperature.
- After each cleaning, disinfection and drying cycle, check that the instrument is dry, clean, functional and undamaged (e.g. no broken insulation, corroded, loose, bent, broken, cracked or dented parts).
- Dry the product if it is wet or damp with clean compressed air.
- Repeat cleaning and disinfection of the product if it remained contaminated.

## XII. Packing

- Place the product on a suitable instrument tray. Make sure all cutting edges are protected.
- Pack the tray according to the intended sterilization procedure.
- Ensure that the packaging provides adequate protection against product contamination during storage.

## XIII. Sterilization

- The device can only be sterilized only when disassembled.
- Validated sterilization procedure: steam sterilization by fractional vacuum.

| | Method | Sterilization cycle | | Drying |
|---|---|---|---|---|
| 1. | Pre-vacuum | 134 °C | 5 min | 30 min |

The autoclave must comply with EN 285 and be validated according to EN ISO 17665.

When sterilizing multiple devices in the autoclave at the same time, make sure that the sterilizer does not exceed the maximum loading capacity specified its manufacturer.

If the user chooses a sterilization procedure other than described above, it is the user's responsibility to validate that sterilization procedure.

## XIV. Service

For repair needs, please contact the manufacturer or the distributor.

Any failure to repair, repair or modify the device by any unauthorized person will void the manufacturer's responsibility and will void the warranty immediately.

## XV. Disposal

Dispose of this product, its parts or packaging in accordance with the applicable national regulations.

Sterilize the product before disposal or recycling!

Manufacturer: EMD Endoszkóp Műszer Gyártó és Kereskedelmi Kft.

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